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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/598,449	08/30/2006	Hamed Aissaoui	AC-26-US	5376

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EXAMINER	
DAVIS, ZINNA NORTHINGTON	
ART UNIT	PAPER NUMBER
1625	
MAIL DATE	DELIVERY MODE
09/08/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/598,449	AISSAOUI ET AL.	
	Examiner	Art Unit	
	Zinna Northington Davis	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10,15 and 17-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10,15, and 17-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *09/01/06;01/09/07;04/08/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 10, 15, and 17-26 are pending.

2. Claims 1-9, 11-14, and 16 have been cancelled.

3. Based upon the response filed June 6, 2009, the requirement for restriction is withdrawn. The claims are examined as a whole.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 15, 17-19, 25 and 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of certain diseases does not reasonably provide enablement for the treatment or prevention of "all disorders or diseases associated with orexin system dysfunctions". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

The Nature of the Invention

The nature of the invention is drawn to claims for treating or preventing a disorder or disease associated with orexin system dysfunctions using a compound formula II. See claim 15 (currently amended).

The State of the Prior Art

The state of the prior art teaches that substituted orexins are found to stimulate food consumption in rats suggesting a physiological role for these peptides as mediators in the central feedback mechanism that regulates feeding behavior (Sakurai T. et al., Cell, 5 1998, 92, 573-585). See the specification.

The predictability or lack thereof in the art

The instant claimed invention is highly unpredictable as discussed below:

It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In re Fisher, 427 F.2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instant claimed invention is highly unpredictable since one skilled in the art would recognize that in regards to therapeutic effects of certain diseases, the possible treatment and prevention of all diseases is unpredictable.

Hence, there is an absence of a showing of correlation between any disease and disorder as claimed which is capable of treatment by the compound of formula (II). One of skill in the art is unable to fully predict possible results from the administration of the

compound of formula (II).

The nature of pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The amount of direction or guidance present

There lacks direction in the instant specification that the compounds of formula (II) can treat certain diseases and disorders. The specification is silent and fails to provide guidance as to whether all these diseases are treatable. The specification fails to provide a correlation between any diseases and disorders.

The presence or absence of working examples

There are not working examples for any diseases or disorders listed in the specification. The specification fails to provide working examples as to how the listed diseases can be used to treat and prevent all diseases. There is no correlation between the diseases and disorders listed at claims 17-19. Additionally, see pages 6 and 7 of the specification.

The breadth of the claims is that the compound of formula (II) can treat or prevent any disease or disorder wherein orexin is required.

The quantity of experimentation needed

The quantity of experimentation needed is undue experimentation. One of skill in the art would need to determine what listed diseases would be benefited and would furthermore then have to determine whether the claimed compounds would provide treatment and prevention of the disease.

The level of the skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Therefore, in view of the Wands factors and In re Fisher (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which diseases can be treated or prevented by the compound encompassed in the instant claims, with no assurance of success.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. At claim 24, is a process of preparation intended?

B. Claim 24 improperly depends upon claim 20. See the reference to crystalline.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 10, 15, 17-23, 25, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Acetlion Pharmaceuticals LTD. [Reference BA (WO 01/68609A), cited by Applicants].

The instantly claimed invention is disclosed. At page 149, see the compound of formula (I). At page 67, see example 110, the compound is disclosed as follows:

2-[1-(2-Phenyl-ethyl)-6,7-dimethoxy-3,4-dihydro-1*H*-isoquinolin-2-yl]-*N*-(pyridin-3-yl-methyl)-acetamide:

The difference between the prior art compound and the instantly claimed compound is R^7 or R^8. For the instantly claimed compounds, R^7 or R^8 represents phenyl. However, the Reference BA teaches the R^7 or R^8 radical represents pyridinyl.

It would have been obvious to one of ordinary skill in the art to replace the heterocyclyl in the pharmaceutical compound of Reference BA with another radical such as phenyl in view of the teaching of equivalence and the expectation of similar pharmaceutical properties. The compounds are deemed obvious variants. Accordingly, the claims are unpatentable therefrom.

10. The Information Disclosure Statements filed September 1, 2006, January 9, 2007, and April 8, 2009 have been considered.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zinna Northington Davis whose telephone number is 571-272-0682.

12. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free)? If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Zinna Northington Davis/
Zinna Northington Davis
Primary Examiner
Art Unit 1625

Znd
09.03.2009